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EXAMINER

PORTNER, V

ART UNIT

PAPER NUMBER

1645

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/598,604

Applicant(s)

Lambl, Barbara B

Examiner

Portner

Art Unit

1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 21, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 20) ☐ Other:

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DETAILED ACTION

Claims 1-17 are pending.

Information Disclosure Statement

1. The information disclosure statement filed March 22, 2001 has been considered prior to first action.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

3. The abstract of the disclosure is objected to because the abstract does not recite a complete sentence. Correction is required. See MPEP § 608.01(b).
4. The disclosure is objected to because of the following informalities: at page 13, line 6 the phrase "(Rule 28(4)EPC)" is recited. To what does this phrase refer?

Appropriate correction is required.

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5. The use of the trademarks at page 12, lines 3 and 7, Flagyl and Floxin, respectively, have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a biologically pure culture of single celled organism given the name of Spiky Rotating Cells. Upon consideration of the specification for a definition of this phrase, the name was found to be arbitrarily assigned to a provisionally classified protozoan. As the label given to the cell culture is only provisionally considered to be a protozoan, it is not clear what the claimed culture is. Any type of cell that is spiky and rotates is claimed. While a broad claim is not

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a basis for indefiniteness, the lack of a clear definition, results in the invention not being distinctly claimed. Claim 1 does not distinctly claim Applicant's invention.

Claim 2 recites a blank line. Information is missing. Clarification of what is intended is requested. The pure culture is claimed based upon the characteristics of the cells of claim 1. As no characteristics are recited in claim 1, claim 2 does not distinctly claim Applicant's invention.

Claim 4 defines the diameter to be approximately 7-8 um. While it is clear what this dimension is, it is not clear to which life cycle stage of a protozoan this measurement corresponds.

Protozoans cycle through more than one stage and can evidence different cell sizes depending on the stage in the cycle. The diameter could correspond to the colony morphology recited in the claim. Clarification of the recited diameter measurement relative to the recited protozoan and colonial morphology is requested.

8. Claims 5-13 are directed to a method of diagnosing an SPR infection. The method recites two methods steps, but neither correlate with diagnosis. The method now claimed only tests for the presence of "SPR". The abbreviation is defined in claim one to be a single celled organism that is spiky and rotates. The specification defines it to be a "provisional protozoa". Bacteria can be spiky due to the presence of cilia and flagella and rotate due to Brownian motion. Protozoa can be spiky due to the presence of cilia, flagella, or pseudopodia and rotate due to the movement produced by the cell's appendages. What the test detects is not distinctly claimed.

9. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The

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omitted steps are: correlation of the test results with diagnosis, as recited in the preamble of the claim.

10. Claims 5-8, 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: what material would provide means for testing and result in diagnosis are not distinctly claimed.

Claims 6, 10 and 12 recite the step of collecting a secretion, and depend from claim 5.

Claim 5 analyzes a sample. Is the secretion and the sample one in the same composition used in the testing step? Clarification or provision for antecedent basis for the word "secretion" is requested.

Claim 9 recites a clarification step defined by two "wherein" statements and recites the phrase "examined by microscopy". It is not clear whether the testing step recited in claim 5, from which claim 9 depends, is to be defined by the phrase "examined by microscopy", or whether claim 9 defines an additional method step separate from the testing step recited in claim 5. If claim 9 defines additional method steps, then the claim should recite the phrase --further comprising--. Clarification of claim 9 is requested.

Claim 17 recites a method of treating any "SPR infection in a patient". The definition provided for "SPR" includes both protozoa, bacteria. The abbreviation "SPR" is defined to be a single celled organism that is spiky and rotates, see claim 1. The specification defines it to be a "provisional protozoa". Bacteria can be spiky due to the presence of cilia and flagella and rotate

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due to Brownian motion. Protozoa can be spiky due to the presence of cilia, flagella, or pseudopodia and rotate due to the movement produced by the cell's appendages. What infection is treated with intraconazole, an antifungal agent, is not distinctly claimed in view of claim 17 being directed to any "SPR" infection. Clarification is requested.

Claim Rejections - 35 U.S.C. § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Please Note: The abbreviation "SPR" is being read as defined in claim 1, to be a single celled organism that is spiky and can rotate. Spiky is being read to include the presence of cilia, flagella or pseudopodia and rotate is being read to mean movement caused by cilia, flagella, pseudopodia or Brownian motion.

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PTA-2129

12. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartskeerl et al (1995)

The claimed invention is directed to a biologically pure culture of a single celled organism that rotates, and has spiky membrane projections.

(Cell composition) Hartskeerl et al disclose a biologically pure culture of a single celled organism (page 278, col. 1, materials and methods, first paragraph), wherein the organism has type I tubular appendages (spiky membrane projections), is motile by protozoan means (see page 282, col. 2, last paragraph). By all comparable data, the cell culture of Hartskeerl et al anticipates the now claimed culture and would inherently comprise the additional cellular characteristics.

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of

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the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ruffer et al (1997)

The claimed invention is directed to a biologically pure culture of a single celled organism that rotates, and has spiky membrane projections.

(Cell composition) Ruffer et al disclose a biologically pure culture of a single celled organism, wherein the organism has two flagella (spiky membrane projections), and rotates during movement (see page 111, col. 1, first paragraph, Introduction section, a wild type strain is disclosed (see materials and methods, page 112, col. 2, first two lines). By all comparable data, the cell culture of Ruffer et al anticipates the now claimed culture.

Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. V IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

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Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

14. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Abou El Seoud (April 1998).

The claimed invention is directed to a biologically pure culture of a single celled organism that rotates, is spherical, has a refractile membrane, spiky membrane projections, motile due to membrane projections, is a protozoan and grows on Diamond medium, 7-8 um in diameter and periodic colonial morphology.

(Cell composition) Abou El Seoud disclose a biologically pure culture of a single celled organism, wherein the organism is known to have a spherical type shape, motile through rotating movements (page 263, introduction), flagellated (a type of spiky membrane projection), is classified as a protozoan and will grow on Diamond medium (abstract). By all comparable data, the cell culture of Abou El Seoud anticipates the now claimed culture and would inherently comprise the additional cellular characteristics.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious

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difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. V IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states “Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer. “The Court further held that “this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art”.

15. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Monteiro-Leal et al (1996).

The claimed invention is directed to a biologically pure culture of a single celled organism that rotates, is spherical, has a refractile membrane, spiky membrane projections, motile due to membrane projections, is a protozoan and grows on Diamond medium, 7-8 um in diameter and periodic colonial morphology.

(Cell composition) Monteiro-Leal et al disclose a biologically pure culture of a single celled organism (see Figure 1, page 207), wherein the organism has multiple spiky membrane projections (ciliar-type beating, page 206, col. 1, third line from bottom; Figure 1, page 207, col. 1), is

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motile with rotating movements (abstract), is classified as a protozoan (page 206, col. 1), which will grow on Diamond medium (page 207, col. 1, materials and methods/cells section).

By all comparable data, the cell culture of Monteiro-Leal anticipates the now claimed culture and would inherently comprise the additional cellular characteristics. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. V IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

16. Claims 1-4 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Relman et al (US Pat. 6,214,548).

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The claimed invention is directed to a biologically pure culture of a single cell organism that is spiky and rotates, is approximately 7-8 um in diameter and classified as a protozoan, as well as a method of diagnosing infection, the method comprising obtaining a sample from a human patient and testing the sample for the presence of the spiky rotating cells.

(Cell composition claims 1-4) Relman et al disclose a biologically pure culture of single celled organisms, referred to as Cyclospora (see col. 2, lines 42-67) that has been characterized to be a human pathogenic protozoan, that forms cystis, and is approximately 7-8 um in diameter (col. 2, line 45; col. 18, lines 14-20).

(Method) The reference discloses a method for diagnosing infection caused by Cyclospora, the method comprising **obtaining** a sample from a patient (see col. 17, lines 25-65; claim 22) and **testing** the sample for the presence of the spiky rotating cells by microscopic inspection or nucleic acids analysis (col. 17, line 29 and Example 2, col. 19-22; claims 1-21). The reference anticipates the now claimed invention.

17. Claims 5-6, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Abou El Seoud (April 1998).

The claimed invention is directed to a method of diagnosing infection in a human patient that comprises obtaining a sample from a patient and testing for the presence of a single celled organism that is motile and a protozoan, wherein the sample is a secretion of the urethra, cervico vaginal region or a skin eruption obtained from a male or female.

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(Method claims) Abou El Seoud discloses a method of diagnosing infection in a human patient that comprises **obtaining** a sample from a patient (page 263, abstract and introduction) and **testing** for the presence of a single celled organism that is motile and a protozoan (page 263, last line, microscopic inspection), wherein the sample is obtained from a male or female (urethritis of both sexes), and is a secretion of the urethra, cervico vaginal region or a skin eruption (cystitis, urogenital wards, epididymitis, page 263 introduction).

Abou El Seoud anticipates the now claimed method of diagnosing infection in a human patient that has “SPR”.

18. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Andrews et al (US Pat. 5,300,491).

The claimed invention is directed to a method of diagnosing infection in a human patient that comprises obtaining a sample from a patient and testing for the presence of a single celled organism that is motile and a protozoan, wherein the sample is obtained from human patient.

(Method claims) Andrews et al disclose a method of diagnosing infection in a human patient that comprises **obtaining** a sample from a patient (col. 8, line 67; col. 13, lines 53; col. 18, lines 27-29) and **testing** for the presence of a single celled organism that is motile and a protozoan (isolates, culture, col. 8, line 68 and col. 9, line 33; col. 13, lines 53-55; col. 18, lines 27-29),

Andrews et al anticipates the now claimed method of diagnosing infection in a human patient that has “SPR”.

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19. Claims 5, 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Caillouette et al (US Pat 5,827,200).

The claimed invention is directed to a method of detecting infection in a female (claim 5) through collecting a cervico vaginal secretion (claim 10) and testing the sample with a pH sensor positioned to come in contact with the sample (claim 11).

(Methods) Caillouette et al disclose and claim a method of detecting infection in a female patient using an instrument for the collection of a vaginal sample, wherein the instrument comprises a pH sensor that comes in contact with the sample (see abstract, Figure 7, and claims 1, 10) and the testing of the sample for a change in pH to aid in the diagnosis of infection (see col. 2, lines 7-9).

The reference inherently anticipates the now claimed invention.

20. Claims 5, 10, 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Caillouette et al (US Pat.5,928,165).

The claimed invention is directed to a method of diagnosing infection in a patient, the method comprising obtaining a vaginal or urethral sample using an instrument, the instrument having a handle, a collection portion and a pH sensor positioned to come in contact with the sample, and testing the sample.

(Method) Caillouette et al disclose and claim a method of detecting infection in a patient, the method comprising **collecting** a sample of a patient and **testing** for infection, wherein the sample

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is collected with an instrument that collects a vaginal or urethral sample (see col. 1, lines 24-25), wherein the instrument comprises a pH sensor that comes in contact with the sample (see abstract, Figures 1, 12, 13, 21, claims 1-26).

The reference inherently anticipates the now claimed invention.

21. Claims 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Mennen (US Pat. 4,108,729).

The claimed invention is directed to a method for diagnosing infection in a human patient, the method comprises obtaining a sample and testing the sample. The testing being carried out with an instrument for the collection of a male urethral secretion, the instrument comprising a sensor positioned to come in contact with the secretion.

(Method) Mennen discloses a method of diagnosing infection in a patient, wherein the patient is a male and the method comprises **collecting** a male urethral secretion containing a single celled organism, wherein collection of the sample is accomplished using an instrument that has a loop shape and comprises a pH sensor and **testing** the secretion for its pH. The secretion is tested with a pH indicator contained within the instrument. (See Figures 1-2 and 8, Figure 1, region 17 defining the handle type region;)

The reference inherently anticipates the now claimed invention.

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22. Claims 5, 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yeh (US Pat. 5,725,373).

The claimed invention is directed to a method for diagnosing infection in a human patient, the method comprising obtaining a sample and testing the sample, wherein the patient has a skin eruption, the secretion is collected with an instrument that comprises a pH indicator positioned to contact with the secretion.

(Method) Yeh disclose a method of diagnosing infection in a human patient, wherein the patient has gum disease and would evidence skin eruptions caused by the disease. The method comprises **collecting** a secretion using an instrument, wherein the instrument comprises a pH sensor that comes in contact with the test sample and **testing** the secretion with a pH indicator contained within the instrument (col. 2, lines 5-10 and figures) .

The reference inherently anticipates the now claimed invention.

23. Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mennen (US Pat. 4,108,729).

The claimed invention is directed to an instrument for the collection of male urethral secretion that has a handle, a collection portion and a pH sensor positioned to come in contact with the secretion.

(Apparatus) Mennen discloses and claims an instrument for the collection of a male urethral secretion, wherein the instrument comprises a pH sensor that comes in contact with the sample

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and a portion that defines a handle type region of the instrument to permit the collection of the sample. (See Figures 1-2 and 8, Figure 1, region 17 defining the handle type region)

The reference inherently anticipates the now claimed invention.

24. Claims 14-15, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Caillouette et al (US Pat.5,928,165).

The claimed invention is directed to an instrument for the collection of a vaginal or urethral secretion and has a handle, a collection portion and a pH sensor positioned to come in contact with the sample.

(Apparatus) Caillouette et al disclose and claim an instrument for the collection of a vaginal or urethral sample, wherein the instrument comprises a pH sensor that comes in contact with the sample (see abstract, Figures 1, 12,13,21, claims 1-26).

The reference inherently anticipates the now claimed invention.

25. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Caillouette et al (US Pat. 5,577,512; or 5,425,377).

The claimed invention is directed to an instrument for the collection of a cervico vaginal secretion that has a handle, a collection portion and a pH sensor positioned to come in contact with the sample.

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(Apparatus) Caillouette et al disclose and claim an instrument for the collection of a vaginal sample, wherein the instrument comprises a pH sensor that comes in contact with the sample (see '512: abstract, Figures 1, 10, 11, claims 1-38; see '377 figures and claims).

The reference inherently anticipates the now claimed invention.

26. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Birthistle et al (1996).

The claimed invention is directed to a method of treating an infection in a patient, wherein the method comprises diagnosing infection and administering metronidazole, wherein the infection is caused by a SPR, wherein SPR is defined to be provisionally a protozoan.

Birthistle et al disclose a method of treating a patient diagnosed with a protozoan infection, protozoans being a type of spiky rotating cell, the method comprising **diagnosing** infection (see col. 1, paragraphs 1-2) and **administering** to the patient an SPR-inhibiting amount of metronidazole (col. 1, paragraph 3), wherein SPR infection is inhibited. The administered metronidazole was disclosed to provide some improvement, thus treating the infection.

Inherently the reference anticipates the now claimed method.

27. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Larson(US Pat. 6,180,136)

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The claimed invention is directed to a method of treating an infection in a patient, wherein the method comprises diagnosing infection and administering ofloxacin, wherein the infection is caused by a SPR, wherein SPR is defined to be provisionally a protozoan.

Larson discloses a method of treating a patient diagnosed with a protozoan infection (see claim 33 and 41), protozoans being a type of spiky rotating cell, the method comprising **diagnosing** infection (claim 41) and **administering** to the patient an SPR-inhibiting amount of a fluoroquinolone, specifically ofloxacin (see claims 35 and 18), wherein SPR infection is treated (claim 33). Inherently the reference anticipates the now claimed method.

28. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Gray (US Pat. 54 74997)

The claimed invention is directed to a method of treating an infection in a patient, wherein the method comprises diagnosing infection and administering intraconazole, wherein the infection is caused by a SPR, wherein SPR is defined to be a spiky rotating single celled organism.

Gray discloses a method of treating a patient diagnosed with a yeast or bacterial infection (see claim 1), bacteria and yeast having irregular cell surfaces, and evidence Brownian motion, the method comprising **diagnosing** infection (claim 1, a human in need of treatment due to infection) and **administering** to the patient an SPR-inhibiting amount of a intraconazole (see all claims), wherein SPR infection is treated (claim 33). Inherently the reference anticipates the now claimed method.

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Claim Rejections - 35 USC § 103

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US Pat. 5,928,165) in view of Kalb et al (US Pat. 5,704,353).

The claimed invention is directed to a method of diagnosing infection, through collecting a sample from a male urethra. The collection instrument comprises a pH indicator and a loop sized shape for the collection of a sample.

See discussion of Caillouette above. The reference discloses a method of diagnosing infection that utilizes a collection instrument that contains a pH indicator, wherein the sample is collected from a human patient urethra, and the collection instrument has the shape of a loop. The reference differs from the instantly claim invention by failing to teach the instrument is formulated for a male urethra.

Kalb et al (US Pat. 5,704,353) suggest the formulation of an instrument for obtaining a male urethra secretion is dependent upon size and can readily be made (see col. 6, lines 64-67 and col. 7, lines 1-3) in an analogous for the purpose of obtaining a sample for urethra secretion pH analysis (see Kalb, claim 3).

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In view of the prior art suggesting the formulation of instruments for the collection of male urethra samples, correctly sized for the patient, it would have been obvious to the person of ordinary skill in the art to obtain a male urethra sample with an instrument as taught by Caillouette formulated for a male, as suggested by Kalb et al, because instruments that provide means for simple, rapid attainment of a biological sample for subsequent evaluation of pH, provides the user of the instrument with means for obtaining a sample for diagnostic testing.

31. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US Pat. 5,928,165) in view of Kalb et al (US Pat. 5,704,353) as applied to claims 7-8 above, and further in view of Sheiness et al (US Pat. 5,776,694).

The claimed invention is directed to a method that comprises obtaining a sample and, testing said sample by pH and microscopic evaluation in order to diagnose infection.

See discussion of Caillouette (US Pat. 5,928,165) in view of Kalb et al above. The references teach a method of diagnosing infection in a human patient through obtaining a male urethral sample and testing the sample by determining the sample pH. The reference differs from the instantly claimed invention by failing to teach the further step of microscopic inspection of the sample that has been diluted in saline.

Sheiness provides and teaches the classical method for diagnosis of an infectious organism through observing the pathogen based upon characteristic motility in secretions mixed

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with saline in a wet mount (see col. 3, lines 13-19) in an analogous art for the purpose of teaching methods of diagnosing infection in human patients.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to diagnose "SPR" infection using a method that comprises obtaining a urethral sample from a male and testing the sample based upon pH and microscopic inspection because classical microbiology has defined identifying characteristics for various microorganisms to aid in the diagnosis of infection and provides efficient means for observing cell rotational movement and the combination of microscopic inspection and pH determination would provide two sources of data to aid in the accurate diagnosis of "SPR" infection.

Conclusion

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
33. Lambl, BB et al (1996) is cited to show microsporia infection in AIDs patients.
34. Suresh, K et al (1993) is cited to show Blastocystis hominis, a protozoa which has a fuzzy coat of upright elements.
35. Zumla et al (1993) is cited to show opportunistic parasites of AIDs patients.
36. Dunn et al (1989) is cited to show Blastocystis homis in pure culture.
37. Eggers et al (US Pat. 6,113,597) is cited to show an electrode device that comprises loops and contacts the sample with saline for the attainment of a patient sample.

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38. Myjak et al (2997) is cited to show the growth of protozoans on Diamond culture media.
39. Rappelli et al (1998) is cited to show T.vaginalis cultured in Diamonds medium, wherein T.vaginalis was associated with M.hominis.
40. Verges (1989) is cited to show Trichomonas in a round, cystic form in women.
41. Sobottka et al (1995) is cited to show Encephalitozoon intestinalis, a human pathogen.
42. Al-Sanori (1996,abstract) is cited to show associated micro flora of urethritis.
43. Lambert, Jr. US Pat. 5,646,114 is cited to show a method of treating protozoan infection.
44. Didier et al (1996) is cited to show Septat intesinalis as a human pathogen.
45. Soule et al (1997) is cited to show Septat intesinalis as a human pathogen.
46. Cali et al (1993) is cited to show Septat intesinalis as a human pathogen.
47. Mennen (US Pat. 4,018,653) is cited to show an instrument for the collection of a urethral sample from a male.
48. McMillan (US Pat.4,951,684) is cited to show a look like collection instrument.
49. Skiffinton et al (US Pat. 5,965,453) is cited to show an instrument for collection of a patient sample and evaluation of pH or color change.
50. Oudewaal (US Pat. 3,822,593) is cited to show an instrument that detects pH in a sample.
51. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner

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can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

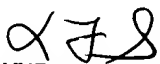
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

July 19, 2001


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